NOT FOR PUBLICATION

**FILED UNDER SEAL**

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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| PURDUE PHARMACEUTICAL PRODUCTS L.P. et al.,<br><br>Plaintiffs,<br><br>v.<br><br>ACTAVIS ELIZABETH LLC, et al.,<br><br>Defendants. | Civil Action No. 12-5311 (JLL) (JAD)<br><br>**OPINION** |

**LINARES, District Judge.**

This matter comes before the Court by way of motion for partial summary judgment (the "Motion") of: 1) invalidity by Defendants, Actavis Elizabeth LLC, (hereinafter "Actavis"), Novel Laboratories, Inc., (hereinafter "Novel"), Par Pharmaceutical, Inc., Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., (collectively "DRL"), and TWi Pharmaceuticals, Inc., (hereinafter "TWi"), as to U.S. Patent No. 8,242,131 (the "'131 patent"); and 2) invalidity by Defendants, Actavis, Novel, and DRL as to certain claims of U.S. Patent No. 7,682,628 (the "'628 patent"). (ECF No. 220).[1] The Court has considered the submissions made in support of and in opposition to the instant motion. Pursuant to Federal Rule of Civil Procedure 78, the Court did not hear oral argument. Based on the reasons set forth below, Defendants' Motion is **DENIED.**

[1] For the purposes of this Opinion, "Defendants" refer to the moving defendants for the correlating arguments. That is, the Court's discussion of indefiniteness refers collectively to "Defendants," Actavis, Novel, Par Pharmaceutical, Inc., DRL, and TWi Pharmaceuticals, Inc. The Court's discussion of anticipation therefore will refer collectively to "Defendants," Actavis, Novel, and DRL.

## I. BACKGROUND

### A. General

Plaintiffs Purdue Pharma L.P., and Purdue Pharmaceutical Products L.P., are the current holders of New Drug Application No. 022328, for sublingual tablets containing 1.75 mg and 3.5 mg of zolpidem tartrate. (ECF No. 36 at ¶ 28). Plaintiffs market the approved drug under the tradename Intermezzo® (hereinafter referred to as "Intermezzo"). (*Id.*). Intermezzo is a drug manufactured for the treatment of insomnia when middle-of-the-night (hereinafter "MOTN") awakening is followed by difficulty returning to sleep. (Compl., ECF No. 1, ¶15). While other approved sleep drugs, such as Ambien®, help patients with difficulty falling asleep, Intermezzo induces sleep in patients suffering from MOTN insomnia.[2] (*See, e.g.*, ECF No. 95 at 7). However, the active ingredient in Intermezzo is zolpidem—the same active ingredient in Ambien®. (*See, e.g.*, *id.*). Nevertheless, Intermezzo uses half the dose of zolpidem than that used in Ambien® and while Ambien® is swallowed as a tablet, Intermezzo delivers zolpidem transmucosally (i.e., sublingually). (ECF Nos. 93 at 8; 95 at 7).

There are four patents covering Intermezzo, two of which are pertinent to this Motion: (1) the '628 Patent entitled "Compositions for delivering hypnotic agents across the oral mucosa and methods of use thereof;" and (2) the '131 Patent entitled "Methods of treating middle-of-the-night insomnia." (ECF No. 152 at 5). Defendants each filed an Abbreviated New Drug Application ("ANDA") pursuant to the Hatch-Waxman Act, seeking FDA approval to sell a generic version of Intermezzo prior to the expiration of the '628 patent. In August of 2012, Plaintiffs responded by suing Defendants for infringement of the applicable patents.

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[2] The parties agree that MOTN insomnia is a "condition wherein a subject, after falling asleep, awakens and has difficulty returning to sleep." (ECF No. 92 at 2).

**B. Defendants' Motion for Summary Judgment**

First, Defendants[3] seek summary judgment as to the invalidity of the '131 patent, arguing that the claim term "without residual sedative effects" is indefinite under 35 U.S.C. §112. (ECF No. 220 at 8). Specifically, Defendants argue that: 1) determining whether or not there are "sedative effects" lacks the required level of certainty; 2) the methods of measuring residual sedative effects are limitless; and 3) "without residual sedative effects" is indefinite because it is outcome-determinative of infringement. (*See generally* ECF No. 220). "Without residual sedative effects" appears in Claims 1 and 12 of the '131 Patent. These claims state the following:

> Claim 1: A method of treating middle-of-the night insomnia in a non-elderly patient without prophylactically administering zolpidem, comprising: dosing the patient with a pharmaceutical composition comprising about 0.5 to about 4.75 mg of zolpidem hemitartrate or a molar equivalent amount of a pharmaceutically acceptable form of zolpidem, wherein the pharmaceutical composition is substantially free of other hypnotic agents, wherein the patient awakens from sleep and desires to resume sleep for less than 5 hours, wherein the step of dosing the pharmaceutical composition is performed after the patient awakens from sleep, and wherein the pharmaceutical composition permits the patient to awaken at a time about four hours after dosing without residual sedative effects.
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> Claim 12: A method of treating middle-of-the-night insomnia in an elderly patient without prophylactically administering zolpidem, comprising dosing the patient with a pharmaceutical composition comprising about 1.5 to 2.5 mg of zolpidem hemitartrate or a molar equivalent amount of a pharmaceutically acceptable form of zolpidem, wherein the pharmaceutical composition is substantially free of other hypnotic agents, wherein the patient awakens from sleep, and desires to resume sleep for less than 5 hours, wherein the step of dosing the pharmaceutical composition is performed after the patient awakens from sleep, and wherein the pharmaceutical composition permits the patient to awaken at a time about four hours after dosing without residual

[3] Referencing Actavis, Novel, Par Pharmaceutical, Inc., DRL, and TWi Pharmaceuticals, Inc.

sedative effects.

This Court construed "without residual sedative effects" to mean "with no or minimal subjective feelings of sedation, as evaluated by: (a) testing acceptably in at least one test exploring psychomotor performance, attention, information processing, and memory used by those of skill in the art; and/or (b) demonstrating plasma levels of zolpidem, at an appropriate time point, below about 20 ng/ml." (Opinion, ECF No. 185 at 5-7). This Court also previously reserved on the issue of indefiniteness as it is more appropriately tackled at summary judgment, or, if necessary, at trial. (Id.).

Defendants[4] also seek summary judgment as to the invalidity of claims 1-6, 8, 9, 12, and 14 of the '628 patent, arguing that PCT Patent Application Publication No. WO/89476 to *Pinney et al.,* (hereinafter "*Pinney*") qualifies as a prior art reference under 35 U.S.C. §102 (b) and anticipates each of these claims. (Defs.' Br., ECF No. 220 at 15). *Pinney* is entitled "Chewing Gums, Lozenges, Candies, Tablets, Liquids, and Sprays for Transmucosal Delivery of Medications and Dietary Supplements." (Id.). To sum up the teachings of *Pinney,* its abstract explains:

> A transmucosal delivery system comprises a carrier for oral administration. A buffer is dispersed within the cavity, and there is sufficient buffer to achieve a predetermined pH within the oral cavity of a user. An active ingredient is dispersed within the carrier. At least a portion of the active ingredient is unionized at the predetermined pH, thereby permitting transmucosal absorption of the active ingredient within the oral cavity.

(ECF No. 220 at Ex. 5). Defendants point the Court to each of the allegedly anticipated claims of the '628 patent and their corresponding *Pinney* disclosure, arguing that these claims of the '628 patent are invalid. (Defs.' Br., ECF No. 220 at 15-16).

[4] Referencing Actavis, Novel, and DRL.

## II. LEGAL STANDARD

Summary judgment is appropriate when, drawing all reasonable inferences in the non-movant's favor, there exists no "genuine dispute as to any material fact" and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1273 (Fed. Cir. 2010).

The moving party is entitled to judgment as a matter of law when the non-moving party fails to make "a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). However, if a reasonable juror could return a verdict for the non-moving party regarding material disputed factual issues, summary judgment is not appropriate. *See Anderson*, 477 U.S. at 242-243 ("At the summary judgment stage, the trial judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial."). With this framework in mind, the Court turns now to Defendants' Motion.

## III. DISCUSSION

### A. Indefiniteness

The U.S. Supreme Court has held that courts should hold a claim to be indefinite and therefore, invalid, "if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments*, No. 13-369, 2014 U.S. LEXIS 3818, at *6 (June 2, 2014). Defendants contend that the relevant claims of the '131 are invalid under 35 U.S.C. § 112, ¶ 2, because the term "without residual sedative effects" is indefinite. 35 U.S.C. § 112, ¶ 2 requires that the specification of a patent "conclude with one or more claims particularly pointing

out and distinctly claiming the subject matter which the applicant regards as his invention." Because claims delineate the patentee's right to exclude, the patent statute requires that the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Otherwise, competitors cannot avoid infringement, defeating the public notice function of patent claims. *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed.Cir.1996) ("[T]he primary purpose of the requirement is 'to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their [respective] rights.' ") (quoting *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369, 58 S.Ct. 899, 82 L.Ed. 1402, (1938)). As always, the party challenging the patent bears the burden of proving invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S.Ct. 2238, 2242, 180 L.Ed.2d 131 (2011).

Defendants argue that the '131 patent claims are indefinite because they "fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). This argument is premised on Defendants' contention that "the numerous and unlimited tests for the presence or absence of residual sedative effects give conflicting, outcome-determinative, results." (Defs.' Br., ECF No. 220 at 2). The Court will first discuss whether Defendants have confirmed that the tests for residual sedative effects give conflicting results before discussing whether this is indeed "outcome-determinative" in the infringement analysis.

**1. Methods for Measuring Residual Sedative Effects: Psychomotor Performance Tests**

This Court construed "without residual sedative effects" to mean "with no or minimal subjective feelings of sedation," and then delineated two methods for evaluating such feelings.

(Opinion, ECF No. 185 at 5-7). That is, "no or minimal subjective feelings of sedation as evaluated by: (a) testing acceptably in at least one test exploring psychomotor performance, attention, information processing, and memory used by those of skill in the art; and/or (b) demonstrating plasma levels of zolpidem, at an appropriate time point, below about 20 ng/ml." (Id.). Defendants first point the Court to tests "exploring psychomotor performance, attention, information processing, and memory," and explain that different methods of testing these functions will produce different levels of residual sedative effects. Defendants cite to Plaintiffs' expert, Dr. David R. Drover, M.D., (hereinafter "Dr. Drover") who stated that "different tests pick up different components of sedation. And so, thus, [the different tests] have different sensitivity to the different types of sedation." (Defs.' Br., ECF No. 220 at 2-3). From here, Defendants ask the Court to conclude that different standard tests give contrasting results for the presence or absence of sedation. (Id.). The Court is not inclined to do so.

Upon closer examination of Dr. Drover's deposition, he actually states "I don't think they are different results … each give me a different piece of information." (Defs.' Br., Ex 12 at 8). In sum, Defendants take issue with the fact that two standard pharmacodynamics tests[5] in the industry, the Choice Reaction Task test ("CRTT") and Digital Symbol Substitution test ("DSST"), show different results at four hours for zolpidem in a study titled "A comparison of the residual effects of zaleplon and zolpidem following administration 5 to 2 h before awakening." (hereinafter the "*Danjou* study" or "*Danjou*"). (Defs.' Br., ECF No. 220 at Ex. 18). Notably perhaps, is the fact that *Danjou* studied a zolpidem dosage of 10mg, whereas no claim of the '131 patent claims administering zolpidem of any dose higher than 4.75 mg in a non-elderly patient. In any event, Dr. Drover again rebuts Defendants' argument for divergent test results, stating "No … [the

[5] Methods of testing psychomotor performance.

different tests] are telling me different things about how zolpidem works, how the sedation ensues, and how the patients perceive that sedation." (Defs.' Br., Ex 12 at 8).

Defendants also ask the Court to analogize Dr. Drover's deposition with the findings in *Honeywell International, Inc. v. International Trade Commission* for indefiniteness, where the specification within a claim did not discuss *which* sample preparation method should be used, and the particular method chosen was "critical to discerning whether [an infringing yarn] has been produced by the claimed process." (emphasis added). 341 F.3d 1332, 1340 (Fed.Cir.2003) (emphasis added). The Court finds *Honeywell* distinguishable in this regard and at this juncture. 341 F.3d 1332 (Fed.Cir.2003).

*Honeywell* involved a patent disclosing "a process for production of a particular multifilament polyester product called polyethylene terephthalate ("PET") yarn" used as a reinforcement for automobile tires. 341 F.3d at 1334. *All claims* in the patent at issue in that case "require[d] that the yarn produced by the claimed process fall within a specified . . . [melting point elevation] at some point during the process." *Id.* at 1335 (emphasis added). The dispute in the case "focused on the method of measuring one claimed feature—the melting point elevation ("MPE")." *Id.* Although there were four methods for preparing PET yarn that were well known to persons of ordinary skill in the art, "neither the claims, the written description [of the patent at issue], nor the prosecution history reference[d] any of the four sample preparation methods that can be used to measure the MPE." *Id.* at 1339. However, this possibility for unlimited methods does not appear in the case at hand. Here, claim construction has delineated two testing mechanisms for residual sedative effects, either of which is acceptable.

Similarly, in *Honeywell*, the court noted that depending upon which method was used, "the calculated MPE for a given sample can vary greatly." *Id.* at 1336. With this in mind, the court held that the claims containing the disputed term "melting point elevation" were "insolubly ambiguous, and hence indefinite" because "the claims, the written description, and the prosecution history fail[ed] to give . . . any guidance as to what one of ordinary skill in the art would interpret the claim to require." *Id.* at 1340. Even if this Court were to overlook Dr. Drover's explanation that the results are not different but they simply "tell [him] different things," a reasonable juror could find that the variation in results when utilizing different measurement techniques, simply arises from the difficulty in measuring "subjective" feelings of sedation, as the claim construction states. *See Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359, 1366-68 (Fed. Cir. 2014) (finding no indefiniteness where "the variation arises from the difficulty in measuring the average diameter of particles that are not perfect spheres.").

Indeed, the Federal Circuit has held that the mere possibility of different results from different measurement techniques does not render a claim indefinite. *Id.* Dr. Drover's deposition is not analogous to *Honeywell* but rather is comparable to the more recent case, *Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014). *Takeda* found no indefiniteness because "the evidence established that *both* methods of measurement accurately report average particle diameter[] [and] the experts agreed that 'the correct but differing particle size results obtained using various instruments are all equally correct, *but each simply may be expressing its correct results in different terms*.'" *Id.* at 1366-68 (emphasis added). At this juncture, Dr. Drover's deposition has, at the very least, created a genuine dispute of fact as to whether or not methods of measuring residual sedative effects produce different results or produce the same results in

supplementary terms. Therefore, the Court cannot award summary judgment as to indefiniteness of Claim 1 or 12.

**2. Methods for Measuring Residual Sedative Effects: Psychomotor Performance Testing v. Plasma Level Testing**

Defendants also turn to the alternative testing method in this Court's construction of "without residual sedative effects," namely, tests for "plasma levels of zolpidem, at an appropriate time point, below about 20 ng/ml." (Opinion, ECF No. 185 at 5-7). Defendants assert that none of their allegedly infringing products have been determined to lack residual sedative effects when using plasma level testing to measure zolpidem in the body. (Defs.' Br., ECF No. 220 at 9). However, when the tests for sedative effects are done by way of psychomotor testing (e.g. DSST), residual sedative effects can be present. Thus, Defendants assert that this contradiction produces results both inside and outside of the Court's claim construction and therefore the claim is invalid as indefinite. However, the Court's claim construction is clear in stating that residual sedative effects can be evaluated by testing acceptably in one psychomotor test *or* demonstrating plasma levels of zolpidem below 20ng/ml. (Opinion, ECF No. 185 at 5-7) (emphasis added). Thus, these divergent results only show that one test produces residual sedative effects and thus the results fall within the claim. This construction uses the word "or" to allow for more than one method of testing for residual sedative effects, and as *Takeda* tells us, there being more than one way to determine residual sedative effects does not render that clear claim language indefinite. *Id.* at 1367.

**3. Outcome Determinative**

Although the Court is unable to conclude, as a matter of law, that the methods for measuring residual sedative effects give substantially different results, for purposes of

completeness, the Court addresses whether or not this would be "outcome-determinative" in the infringement analysis. The Court finds that Defendants have failed to present, on the current Motion, clear and convincing evidence that the method chosen to test for residual sedative effects is in fact outcome-determinative in the infringement analysis. That is, the choice of one method over another has not been shown to make enough difference to render the patent indefinite. Similarly, Defendants point the Court to no data suggesting that the results of the psychomotor studies would likely diverge at the doses actually claimed by the '131 patent. Instead, Defendants cite to the *Danjou* study involving a 10mg dose of zolpidem, whereas the '131 patent does not claim any dose of zolpidem over 4.75mg. Even assuming *arguendo* that divergent results were present, the particular test used is not proven "critical" to discerning infringement at a given zolpidem dose. *Quoting Takeda* 743 F.3d 1359, 1367 n.4. As explained thoroughly above by Dr. Drover, the test chosen is not critical because, in his opinion, it merely gives different information and cannot therefore determine infringement. Without clear and convincing evidence before the Court, at this time, the method used to test for residual sedative effects cannot be said to be "outcome-determinative."

**B. Anticipation**

Anticipation, though a question of fact, may be resolved on summary judgment if no genuine issue of material fact exists. *Ormco Corp. v. Align Tech., Inc.,* 498 F.3d 1307, 1319 (Fed.Cir.2007). An invention is anticipated under 35 U.S.C. § 102(b) if it "was patented or described in a printed publication in this or a foreign country ... more than one year prior to the date of the application for patent in the United States." "A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention." *Schering Corp. v. Geneva Pharm.,* 339 F.3d 1373, 1377 (Fed.Cir.2003). Such disclosure can be explicit or

inherent in the prior art. *See Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed.Cir.1991). However, mere disclosure of each and every limitation of a claim is not enough for anticipation. Leader Technologies, Inc. v. Facebook, Inc., 770 F. Supp. 2d 686, 703 (D. Del. 2011) aff'd, 678 F.3d 1300 (Fed. Cir. 2012). "An anticipating reference must enable that which it is asserted to anticipate." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1345 (Fed.Cir.2008).

Furthermore, a single prior art reference must also disclose the limitations as arranged in the claim. *See Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed.Cir.2008) ("[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102."). As with all challenges to the validity of a patent, the party seeking to invalidate a patent bears the burden of proving anticipation by clear and convincing evidence. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed.Cir.1986).

**1. Claim 1 of the '628 Patent**

Claim 1 of '628 patent recites:

> A method for treating insomnia, comprising the steps of: administering a solid pharmaceutical composition comprising zolpidem or a pharmaceutically acceptable sale thereof to a subject prone to insomnia, the pharmaceutical composition further comprising a buffer, wherein the buffer raises the pH of saliva to a pH of about 7.8 or greater, wherein zolpidem is absorbed across a permeable membrane of the subject's oral mucosa, and wherein at least 75% of the solid pharmaceutical composition dissolves within 10 minutes or less within an oral cavity following administration.

Defendants attempt to present their argument for anticipation by dividing Claim 1 of the '628 patent into 6 limitations and listing the coorelating *Pinney* disclosures. (Defs.' Br., ECF No. 220 at 16-17). The Court takes the three *disputed* limitations in turn.

Plaintiffs oppose this Motion and argue that as it relates to Claim 1, *Pinney* fails to disclose:

1) zolpidem as a sleep enhancer; 2) zolpidem as a method for treating a subject prone to insomnia; and 3) treatment of insomnia generally (as opposed to simply disclosing those substances which are sleep enhancers). (Pls.' Br., ECF No. 245 at 27). Thus, for the purposes of the analysis of Claim 1, the Court examines the first two limitations which state: "a method of treating insomnia comprising the steps of" and "administering a solid pharmaceutical composition comprising zolpidem … to a subject prone to insomnia." (citation omitted).

Defendants argue that "a method of treating insomnia comprising the steps of" is anticipated by the explicit disclosure in *Pinney* which states "Exemplary of the many categories of active medicants that are suitable for transmucosal delivery are… sleep enhancers." (Defs.' Br., ECF No. 220 at 16). Plaintiffs argue that the term "sleep enhancers" conveys nothing to a POSA about how an active substance may be used to treat insomnia such as symptoms, conditions, dosages or desired therapeutic effect. (Pls.' Br., ECF No 245 at 27).

Defendants next argue that "administering a solid pharmaceutical composition comprising zolpidem … to a subject prone to insomnia" is anticipated by Pinney's disclosure which states "Exemplary of the many medicants suitable for transmucosal delivery are…zolpidem." (Defs.' Br., ECF No. 220 at 16). Further, Defendants state that a POSA reading *Pinney*, if interested in formulating a drug to treat insomnia, would immediately discount all of the medicants listed in *Pinney* except for zolpidem. (Id. at 18). Plaintiffs however, opine that because *Pinney* fails to disclose zolpidem as a sleep enhancer, and because zolpidem is a molecule and not a method of treatment for insomnia, Claim 1 of the '628 patent is not *fully* disclosed. (Pls.' Br., ECF No 245 at 27) (emphasis added).

While recognizing that a disclosure can be inherent rather than explicit in the prior art to anticipate a claim, the Court finds that a genuine dispute of material fact exists as to whether or

not a POSA would understand *Pinney* to disclose a "method of treating insomnia." *See Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed.Cir.1991). For example, Plaintiffs' expert, Dr. Meir Kryger, M.D., (hereinafter "Dr. Kryger") articulates why *Pinney's* failure to reference "insomnia" is detrimental to Defendants argument that Claim 1 of the '628 is anticipated. Dr. Kryger explains that zolpidem is mentioned within a "laundry list" of medications and is not disclosed as a sleep enhancer. (Kryger Opp. Decl., Ex. 4 ¶ 443). Additionally, in order for a POSA to know that they could use *Pinney's* formulation as a method of treating insomnia, Dr. Kryger states that *Pinney* would have to disclose details such as the amount of active ingredient to be used or under what conditions the active ingredient could be used. (Id.).

Dr. Kryger exemplifies this through a sample which the Court finds compelling. He explains that to understand why simply using the words "sleep enhancers" independently is an insufficient disclosure for the elements of Claim 1, take for example the (also disclosed by *Pinney*) drugs morphine and scopolamine. (Id. ¶ 444 ). Dr Kryger explains that while historically the combination of these two drugs has been used for "twilight sleep," a form of sedation used during certain medical procedures, and is thus a "sleep enhancer," it would be exceedingly dangerous to use this combination as a "a method for treating insomnia" because too high a dose could cause the patient to stop breathing. (Id.). The Court finds no reason that a POSA may make a similar error with zolpidem when analyzing *Pinney*, and Defendants present no evidence to the contrary.[6] With this factual dispute as to a POSA's interpretation of *Pinney's* disclosure in mind, the Court must deny summary judgment as to the anticipation of Claim 1, because the single prior art

[6] The Court remains cognizant of precedent stating that "[t]o serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence." Cont'l Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). However, "such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." (Id.). Plaintiffs have articulated a genuine dispute of material fact in this regard where a reasonable jury could find that a POSA would not have understood *Pinney* to disclose a method for treating insomnia.

reference, *Pinney,* fails to disclose *each and every limitation* of the claimed invention. *Schering Corp. v. Geneva Pharm.,* 339 F.3d 1373, 1377 (Fed.Cir.2003) (emphasis added).

For purposes of completeness, the Court also analyzes the remaining disputed limitation of Claim 1, which states "wherein zolpidem is absorbed across a permeable membrane of the subject's oral mucosa." A view of *Pinney* as whole rather than combining elements of the prior art as Defendants seek to do, enlightens the Court in this regard. Generally, *Pinney* explains that medications contained in lozenges (for example) can be delivered in a multi-phase mode where the compositions also contain buffer systems that facilitate oral absorption. (Defs.' Br., Ex. 5 at 2). The invention in *Pinney* is summarized as "a transmucosal delivery system … comprises a carrier suitable for oral administration." (Id. at 4). However, *Pinney* also explains that "many active ingredients display chemical properties that *prevent* transmucosal absorption." (Id. at 2) (emphasis added). Thus, while true that *Pinney* mentions zolpidem (and only in the list of claims) it does not present any findings that zolpidem can be absorbed transmucosally. *See e.g. id. at 18.*

Defendants compare the aforementioned limitation of Claim 1 to its alleged comparable in *Pinney* which states: "The buffer system is released simultaneously with the medicant(s) and dietary supplements, thereby facilitating transmucosal and buccal absorption of active ingredient(s)." (Defs.' Br., ECF No. 220 at 17). The dispute of material fact here, is that Defendants attempt to incorporate zolpidem *by reference* rather than pointing the Court to any disclosure by *Pinney* that zolpidem can be absorbed through a person's oral mucosa. In fact, *Pinney* fails to do so. The Court has thoroughly reviewed *Pinney* and finds that a reasonable juror could conclude that reading *Pinney* as a POSA would not disclose the administration of *zolpidem* as in the '628 patent.

**2. Claims 2-6, 8, 9, 12 and 14 of the '628 Patent**

In view of the fact that the Court cannot find that *Pinney* "discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited" in Claim 1, Claims 2-6, 8, 9, 12 and 14 also fail to be anticipated by *Pinney* as they are dependent on Claim 1. *See Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed.Cir.2008). For example, Claim 2 of '628 patent recites: "*The method of claim 1,* wherein the solid pharmaceutical composition further comprises a binder and a disintegrating agent," and Claim 12 states: "*The method of claim 1*, wherein the solid pharmaceutical composition is a tablet." (emphasis added). Without a finding that *Pinney* anticipates Claim 1 of the '628 patent (by clear and convincing evidence), the Court cannot hold that *Pinney* anticipates any dependent claim (Claims 2-17) at this time.

## IV. CONCLUSION

For the reasons set forth above, Defendants' motion for partial summary judgment, (ECF No. 220), is **DENIED**.

An appropriate Order accompanies this Opinion.

Date: October 23, 2014

Jose L. Linares
United States District Judge